REMARKS

I. Status of the Claims

With this amendment, claims 1-77 are pending in the present application. Claims 1-9 and 24-77 are withdrawn. Claims 10-23 are under examination.

II. Rejection under 35 U.S.C. 103(a)

Claims 10-17 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Guo *et* al. (1994), in view of Moviglia (1996). Applicants respectfully traverse the rejection and its supporting remarks.

The Examiner has dismissed the applicants assertion that the fundamental lack of predictability when dealing with the immune system generally and the cancer vaccination in particular by stating that "[w]ith regard to unpredictability of success, Applicant is again reminded that the claims are directed to a product, which is obvious to make based on the cited references, not a method of achieving a therapeutic effect, and the therapeutic effect of the claimed product is not part of the claim limitation." See Office Action dated 4/04/08, page 5, lines 18-21. Applicants are uncertain of the basis for the Examiner's assertion that unpredictability with regard to a claimed composition can be ignored. Applicants therefore respectfully request that the Examiner cite to the section of the MPEP that supports the position taken by the Examiner so that the applicants can better understand the rejection.

However, the Examiner in the obviousness rejection asserted that "[o]ne of ordinary skill in the art would be motivated to do so because the observation of CD8+ cells activated by TBH is required for TBH antitumor therapeutic activity." See Office Action dated 6/12/07, page 4, lines 7-9. Thus, the Examiner's stated reason for modifying Guo was based upon an asserted therapeutic activity. Further more, MPEP2141 (pg 2100-119, Rev. 6, Sept. 2007) provides guidelines for determining obviousness lists the different rationales for modifying or combining references:

(A)Combining prior art elements according to known methods to yield ***predictable results***;

(B)Simple substitution of one known element for another to obtain ***predictable results***;

(C)Use of ***known technique*** to improve ***similar devices*** (methods, or products) in the same way;

(D)Applying a known technique to a known device (method, or product) ready for improvement to yield ***predictable results***;

(E)"Obvious to try" – choosing from a finite number of identified, predictable solutions, with ***a reasonable expectation of success***;

(F)Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are ***predictable*** to one of ordinary skill in the art;

(G)Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Rationales (A), (B), (D), and (F) all expressly state that the modification or combination must be predictable. These rationales are not available as the outcome when dealing with cancer vaccines is unpredictable. Rationale (C) states that it must be a known technique for improving a device, method or product. Stimulation of CD8+ cells *ex vivo* is not a known technique for improving cancer vaccines, especially since, as far as applicants are aware, there is no approved cancer vaccine yet on the market in the US, so there is nothing to improve yet. Rationale (E) is not available as there are a vast multitude of techniques that are being tested to develop an effective cancer vaccine, of which tumor/b-cell hybrids, until the present invention, was but one avenue that had not yet proved workable. Even if there were a limited number of possible avenues for developing an efficacious cancer therapeutic, there would still need to be a reasonable expectation of success, i.e., predictability. Finally, rationale (G) is the traditional "teaching, suggestion, or motivation" test that has always required a reasonable expectation of success, i.e., predictability.

Thus, the Examiner either needs to provide a citation in the MPEP which states that compositions do not need to predictably produce some useful result or needs to provide some evidence that formulation of cancer vaccines is a routine and predictable art.

If the Examiner is not able to provide either, applicants respectfully request the withdrawal of the rejection of claims 10-17 under 35 U.S.C. § 103(a).

III. Rejection under 35 U.S.C. 103(a)

Claims 18-23 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Guo *et* al. (1994), in view of Moviglia (1996) and Gong *et al.* (WO 01/59073). Applicants respectfully traverse the rejection and its supporting remarks.

As discussed above, the lack of predictability in the art obviates any obviousness rejection.

Therefore, unless the Examiner can provide a citation in the MPEP which states that compositions do not need to predictably produce some useful result or some evidence that formulation of cancer vaccines is a routine and predictable art, applicants respectfully request the withdrawal of the rejection of claims 18-23 under 35 U.S.C. § 103(a).

IV. Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **545872000100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: May 1, 2009

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